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Registration Decision RD2014-05

p-Menthane-3,8-diol and Related Oil of Lemon Eucalyptus Compounds

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Registration Decision for p-menthane-3,8-diol and related oil of lemon eucalyptus compounds

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale of the technical p-menthane-3,8-diol and related oil of lemon eucalyptus compounds (sold under the trade name Citriodiol), and the personal insect repellents Citrepel Insect Repellent 30 and Natrapel Insect Repellent, containing the technical grade active ingredient p-menthane-3,8-diol and related oil of lemon eucalyptus compounds, for use to repel mosquitoes.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2013-04, *p-Menthane-3,8-diol and Related Oil of Lemon Eucalyptus Compounds*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for p-menthane-3,8-diol and related oil of lemon eucalyptus compounds and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2013-04. This decision is consistent with the proposed registration decision stated in PRD2013-04.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2013-04, *p-Menthane-3,8-diol and Related Oil of Lemon Eucalyptus Compounds* that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act*"...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What is p-menthane-3,8-diol and related oil of lemon eucalyptus compounds?

Citriodiol (p-menthane-3,8-diol and related oil of lemon eucalyptus compounds) is used to formulate skin-applied personal insect repellents. The mode of action of p-menthane-3,8-diol and related oil of lemon eucalyptus compounds for repelling mosquitoes is not known. However, in laboratory studies p-menthane-3,8-diol and related oil of lemon eucalyptus compounds has been seen to repel mosquitoes as they approach the zone near the treated skin, rather than act as a masking agent so that they do not find the host.

Health Considerations

Can approved uses of p-menthane-3,8-diol and related oil of lemon eucalyptus compounds affect human health?

p-Menthane-3,8-diol and related oil of lemon eucalyptus compounds is unlikely to affect human health when it is used according to label directions.

Potential exposure to p-menthane-3,8-diol and related oil of lemon eucalyptus compounds may occur when handling and applying the end-use products, Citrepel Insect Repellent 30 and Natrapel Insect Repellent, which are registered as personal insect repellents for repelling mosquitoes. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

In laboratory animals, p-menthane-3,8-diol and related oil of lemon eucalyptus compounds, was of low acute toxicity via the oral and dermal routes of exposure, and slightly acutely toxic via inhalation exposure. It was also a slight skin irritant, a moderate eye irritant, and not a skin sensitizer. Consequently, the hazard signal words, 'WARNING – EYE IRRITANT' and 'CAUTION POISON' are required on the label. The two end-use products are expected to be of low acute toxicity via the inhalation route of exposure but otherwise have similar toxicity profiles to the technical grade active ingredient. Consequently, the labels for the two end-use products require the hazard signal words, 'WARNING – EYE IRRITANT'. Based on the container sizes for the two end-use products, it is possible that a young child could consume enough of either product to experience significant toxicity. Therefore, for container sizes of 75 mL or larger, the hazard signal words, 'CAUTION POISON' are required on the labels.

Risks in Non-Occupational/Consumer Environments

Estimated risk for non-occupational / consumer exposure is not of concern provided that directions specified on the label are observed.

Exposure to individuals coming in contact with Citrepel Insect Repellent 30 and/or Natrapel Insect Repellent is not expected to result in unacceptable risk when used according to the label directions.

Precautionary (for example, use only on children 3 years of age or older) and hygiene statements on the label are considered sufficient to protect individuals from any unnecessary risk due to consumer exposure.

Environmental Considerations

An environmental assessment was not required for the use as a personal insect repellent.

Value Considerations

What is the value of Citrepel Insect Repellent 30 and Natrapel Insect Repellent?

Citrepel Insect Repellent 30 and Natrapel Insect Repellent are skin-applied insect repellents that repel mosquitoes for 4 to 6 hours following application. These products will provide additional choice for mosquito repellent users.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the label of Citrepel Insect Repellent 30 and Natrapel Insect Repellent to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

The signal words 'WARNING-EYE IRRITANT', 'CAUTION POISON', and 'PREVENT ACCESS BY UNAUTHORIZED PERSONNEL' are required on the principal display panel for the technical grade active ingredient label. The statements, 'PREVENT ACCESS BY UNAUTHORIZED PERSONNEL. Causes eye irritation. DO NOT get in eyes. Harmful if inhaled. Avoid inhaling or breathing sprays.' are required for the PRECAUTIONS section of the secondary display panel for the technical grade active ingredient.

The signal words, 'WARNING-EYE IRRITANT' and 'KEEP OUT OF REACH OF CHILDREN' are required on the principal display panels of the labels for the two end-use products and the signal words 'CAUTION POISON' are also required on the principal display for end-use products sold in containers 75 mL or larger in size. The statements, 'KEEP OUT OF REACH OF CHILDREN. Causes eye irritation. DO NOT get in eyes. are required for the PRECAUTIONS section of the secondary display panels on the labels for the two end-use products. For container sizes of 75 mL or larger, the statement, 'Harmful if swallowed' is also required on the secondary display panels of the labels for the two end-use products.

Since Citrepel Insect Repellent 30 and Natrapel Insect Repellent are applied directly to the skin, the secondary display panel of both end-use product labels must state 'Apply sparingly, not under clothing and only when necessary', 'After returning from the outdoors, wash product from all exposed skin and wash contaminated clothing', 'Do not allow children to apply this product to themselves', and 'Do not apply to the hands of children.' The precautionary statement 'DO NOT use on children under 3 years of age' is required on the secondary display panel of both Citrepel Insect Repellent 30 and Natrapel Insect Repellent.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2013-04, *p-Menthane-3,8-diol and Related oil of Lemon Eucalyptus Compounds*) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision, www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/publi-regist/index-eng.php#rrd) or contact the PMRA's Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act*.